510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K040464

B. Purpose for Submission:
New Device

C. Analytes:
THC (marijuana metabolite), benzoylecgonine, morphine, propoxyphene, oxycodone, secobarbital, and oxazepam

D. Type of Test:
Qualitative enzyme immunoassay

E. Applicant:
Amedica Biotech, Inc.

F. Proprietary and Established Names:
Amedica Drug Screen THC/COC, OPI300, PPX, OXY, BAR/BZO Test

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.3870
   21 CFR § 862.3250
   21 CFR § 862.3650 (opiates)
   21 CFR § 862.3700
   21 CFR § 862.3650 (oxycodone)
   21 CFR § 862.3150
   21 CFR § 862.3170
2. Classification:
   II

3. Product Code:
   LDJ (Cannabinoid Test System)
   DIO (Cocaine and Cocaine Metabolite Test System)
   DJG (Opiate Test System)
   JXN (Propoxyphene Test System)
   DJG (Opiate Test System - oxycodone)
   DIS (Barbiturate Test System)
   JXM (Benzodiazepine Test System)

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:

   The Amedica Drug Screen THC/COC, OPI300, PPX, OXY, BAR/BZO Test is an in vitro diagnostic test for the rapid detection of THC, benzoylecgonine, morphine, propoxyphene, oxycodone, secobarbital and oxazepam in human urine at the following cut-off concentration

THC	11-nor-Δ^9-THC-9-COOH	50 ng/ml
COC	benzoylecgonine	300 ng/ml
OPI	morphine	300 ng/ml
PPY	propoxyphene	300 ng/ml
OXY	oxycodone	100 ng/ml
BAR	secobarbital	300 ng/ml
BZO	oxazepam	300 ng/ml

   This test kit is used to obtain a visual, qualitative result and is intended for use in laboratories and workplaces by trained users. It is not intended for over the counter sale. For in vitro diagnostic use

   Minimum training for operators is defined as those individuals who have received instructions for drugs of abuse testing from a physician or medical review officer. Operators may be lay users with no prior experience in running laboratory tests, but who are expected to perform at least 5 tests per week. Training should cover a variety of topics such as the value of confirmation testing, how to obtain confirmation testing, false positive results, false negative results, and quality control procedures. The sponsor recommends that operators take a written and practical exam before performing any testing and that employers keep documentation of the training.

3. Special condition for use statement(s):

   The Amedica Drug Screen THC/COC, OPI300, PPX, OXY, BAR/BZO Test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Tests for barbiturates, benzodiazepines, and opiates cannot distinguish between abused drugs and certain prescribed medications.

Certain foods or medications may interfere with tests for opiates and cause false positive results.

4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

I. Device Description:

The Amedica Drug Screen THC/COC, OPI300, PPX, OXY, BAR/BZO Test uses a nitrocellulose strip in a dip test, cassette (test card) test, and cup test formats. The only difference between the three strips is the length, where the dip test is 84 mm, the cassette test 59 mm, and the cup test 56 mm.

In the dipstick format, operators dip the test strip into the urine and the reaction is initiated by movement of the sample through the test strip.

In the cassette format, operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

In the cup format, test strips are incorporated into the sides of the test cup. Addition of the urine to the test cup brings the test strips in contact with the sample and the sample begins migrating up the test strip. The sponsor recommends a minimum urine volume of 30 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Amedica Drug Screen THC Test
   Amedica Drug Screen Cocaine Test
   Rapid Opiates Test
   Instant-View Propoxyphene Test
   Branan Oxycodone Test
   Amedica Drug Screen MDMA, BAR, BZO, MTD, TCA Test
2. Predicate K number(s):
   k022955
   k022954
   k020716
   k022915
   k030113
   k031497

3. Comparison with predicate:

When compared to the predicates, the candidate device is for the qualitative determination of the same seven analytes in the same matrix, and utilizes the same cutoff concentrations. All of the predicates and the candidate device are visually-read single use devices.

The reagent formulations vary between the predicates and the candidate device.

Similarities		
Item	**Device**	**Predicate**
Type of Test	Single-Use, Qualitative Immunochromatographic Assay	Same
Cutoffs	THC: 50 ng/mL Cocaine Metab: 300 ng/mL Opiates: 300 ng/mL Propox: 300 ng/mL Oxycod: 100 ng/mL Barb: 300 ng/mL Benz: 300 ng/mL	Same
Number of Analytes	THC Cocaine Metab Opiates Propox Oxycod	Predicate measures THC Only Predicate measures Cocaine Metab Only Predicate measures Opiates Only Predicate measures Propoxyphene Only Predicate measures Oxycodone Only
Differences		
Item	**Device**	**Predicate**
Number of Analytes	Barbs plus six other analytes Benz plus six other analytes	Predicate measures only Barbs and Benzos Predicate measures only Barbs and Benzos
Test Formats	Dipstick, Cassette, and Cup	Dipstick and/or Cassette and/or Cup

K. Standard/Guidance Document Referenced (if applicable):

The sponsor referenced the following guidance document(s) in their submission:

Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests, published December 2003.

The sponsor indicated deviation from this guidance in regards to interference testing.

L. Test Principle:

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The test region of the strips contains protein conjugated to THC, benzoylecgonine, morphine, propoxyphene, oxycodone, barbiturates, and benzodiazepines. The coated pad below the test region contains antibodies to THC, benzoylecgonine, morphine, propoxyphene, oxycodone, barbiturates, and benzodiazepines.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact. Goat anti-rabbit antibodies in the control region combine with a rabbit antibody gold complex to produce a colored product.

The user is instructed in the Package Insert that a very faint line in the test region is to be interpreted as a negative result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

    Samples used for the precision study consisted of drug free urine spiked with 11-nor-Δ^9-THC-9-COOH, benzoylecgonine, morphine, propoxyphene, oxycodone, secobarbital, and oxazepam. The sponsor states that the drug concentration was confirmed by GC-MS by the vendor. The testing was done on-site in the sponsor's laboratory. Three operators, who are from the manufacturer's staff, performed the testing over 20 days using three lots of the assay. Two replicates were run per day.

Results of the study are presented below:

Cannabinoid (THC) Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
25	180	180/0
37.5	180	180/0
50	180	77/103
62.5	180	39/141
75	180	0/180

Cocaine Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	180	180/0
225	180	180/0
300	180	94/86
375	180	58/122
450	180	0/180

Opiates Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	180	180/0
225	180	180/0
300	180	94/86
375	180	53/127
450	180	0/180

Propoxyphene Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	180	180/0
225	180	180/0
300	180	94/86
375	180	55/125
450	180	0/180

Oxycodone Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
50	180	180/0
75	180	180/0
100	180	95/85
125	180	37/143
150	180	0/180

Barbiturates Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	180	180/0
225	180	180/0
300	180	101/79
375	180	57/123
450	180	0/180

Benzodiazepines Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	180	180/0
225	180	180/0
300	180	112/68
375	180	57/123
450	180	0/180

The sponsor also provided precision data collected at three workplace sites in order to support a workplace claim. A different operator collected the data at each site and each operator completed the study in one day. Combined results were as follows:

Cannabinoid (THC) Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
25	30 (10 per site)	28/2
37.5	30 (10 per site)	23/7
50	30 (10 per site)	18/12
62.5	30 (10 per site)	4/26
75	30 (10 per site)	0/30

Cocaine Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	30 (10 per site)	29/1
225	30 (10 per site)	21/9
300	30 (10 per site)	19/11
375	30 (10 per site)	6/24
450	30 (10 per site)	0/30

Opiates Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	30 (10 per site)	30/0
225	30 (10 per site)	23/7
300	30 (10 per site)	22/8
375	30 (10 per site)	5/25
450	30 (10 per site)	0/30

Propoxyphene Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	30 (10 per site)	30/0
225	30 (10 per site)	25/5
300	30 (10 per site)	24/8
375	30 (10 per site)	6/24
450	30 (10 per site)	0/30

Oxycodone Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
50	30 (10 per site)	30/0
75	30 (10 per site)	26/4
100	30 (10 per site)	24/6
125	30 (10 per site)	2/28
150	30 (10 per site)	0/30

Barbiturates Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	30 (10 per site)	30/0
225	30 (10 per site)	28/2
300	30 (10 per site)	29/1
375	30 (10 per site)	6/24
450	30 (10 per site)	3/27

Benzodiazepines Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	30 (10 per site)	30/0
225	30 (10 per site)	21/9
300	30 (10 per site)	24/6
375	30 (10 per site)	5/25
450	30 (10 per site)	0/30

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

Control materials are required but are not specifically identified in the labeling.

The device has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. Detection limit:

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result.

To determine the analytical sensitivity, 25 replicates were run at drug concentrations from negative to 3X cutoff. NOTE: for the purposes of this experiment, a very faint line in the test region was interpreted as a borderline result near the cutoff. The user is instructed in the Package Insert that a very faint line in the test region is to be interpreted as negative when testing clinical samples.

THC Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
25	25	25	0	0
37.5	25	10	15	0
50	25	0	13	12
62.5	25	0	5	20
75	25	0	0	25
150	25	0	0	25

COC Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
150	25	25	0	0
225	25	9	16	0
300	25	0	14	11
375	25	0	8	17
450	25	0	0	25
900	25	0	0	25

OPI Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
150	25	25	0	0
225	25	12	13	0
300	25	0	14	11
375	25	0	7	18
450	25	0	0	25
900	25	0	0	25

PPY Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
150	25	25	0	0
225	25	11	14	0
300	25	0	15	10
375	25	0	5	20
450	25	0	0	25
900	25	0	0	25

OXY Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
50	25	25	0	0
75	25	9	16	0
100	25	0	10	15
125	25	0	8	17
150	25	0	0	25
300	25	0	0	25

BAR Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
150	25	25	0	0
225	25	8	17	0
300	25	0	14	11
375	25	0	9	16
450	25	0	0	25
900	25	0	0	25

BZO Conc. (ng/ml)	# Tested	# Negative	# Cut-Off (borderline)	# Positive
0	25	25	0	0
150	25	25	0	0
225	25	9	16	0
300	25	0	14	11
375	25	0	8	17
450	25	0	0	25

900	25	0	0	25

Based on this data, the sensitivity of the assay to the seven analytes is as follows:

THC: 50 ng/ml
COC: 300 ng/ml
OPI: 300 ng/ml
PPY: 300 ng/ml
OXY: 100 ng/ml
BAR: 300 ng/ml
BZO: 300 ng/ml

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,500
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	50
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	50
Δ^8-Tetrahydrocannabinol	8,000
Δ^9 –Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000

Cocaine

Compound	Response equivalent to cutoff in ng/mL
Benzoylecogonine	300
Cocaine	50,000
Ecgonine	>100,000
Ecgonine Methyl Ester	>100,000

Opiates

Drug compound	Response equivalent to cutoff in ng/mL
6-monoacetylmorphine	300
Codeine	300
Hydrocodone	3,000
Hydromorphone	3,000
Morphine	300
Ethylmorphine	2,000

Propoxyphene

Drug compound	Response equivalent to cutoff in ng/mL
Propoxyphene	300
Norpropoxyphene	20,000

Oxycodone

Drug compound	Response equivalent to cutoff in ng/mL
Oxycodone	100
Oxymorphone	80,000

Barbiturates

Compound	Response equivalent to cutoff in ng/mL
Secobarbital	300
Phenobarbital	300
Butalbital	3000
Pentobarbital	400
Alphenal	400
Amobarbital	2000
Aprobarbital	300
Barbital	300
Butabarbital	300

Benzodiazepines

Compound	Response equivalent to cutoff in ng/mL
Alprazolam	200
Chlordiaepoxide	500
Diazepam	300
Oxazepam	300
Clonazepam	50,000
Flunitrazepam	1500
Nitrazepam	20,000
Bromazepam	1500
Clobazam	400
Estazolam	500
Flurazepam	1000
Lorazepam	3000
Lometazepam	10,000
Medazepam	50,000
Nordiazepam	400
Prazepam	5000
Temazepam	3000
Triazolam	50,000

The following compounds were evaluated for potential positive and/or negative interference with the assay.

The compounds were dissolved in 50% cutoff samples to the concentration of 100 ug/ml to evaluate any positive interference effects. An unaltered sample was used as a control. Results are listed below

Compound	THC	COC	OPI	PPX	OXY	BAR	BZO
Control	-	-	-	-	-	-	-
Acetaminophen	-	-	-	-	-	-	-
Acetone	-	-	-	-	-	-	-
Albumin	-	-	-	-	-	-	-
Ampicillin	-	-	-	-	-	-	-
Amitriptyline	-	-	-	-	-	-	-
Aspartame	-	-	-	-	-	-	-
Aspirin	-	-	-	-	-	-	-
Atropine	-	-	-	-	-	-	-
Benzocaine	-	-	-	-	-	-	-
Bilirubin	-	-	-	-	-	-	-
Caffeine	-	-	-	-	-	-	-
Chloroquine	-	-	-	-	-	-	-
Chlorpheniramine	-	-	-	-	-	-	-
Creatine	-	-	-	-	-	-	-
Dexbrompheniramine	-	-	-	-	-	-	-
Dextromethorphan	-	-	-	-	-	-	-
4-Dimethylamino antipyrine	-	-	-	-	-	-	-
Dopamine	-	-	-	-	-	-	-
(+/-)-Ephedrine	-	-	-	-	-	-	-
Erythromycin	-	-	-	-	-	-	-
Ethanol	-	-	-	-	-	-	-
Furosemide	-	-	-	-	-	-	-
Guaiacol Glyceryl Ether	-	-	-	-	-	-	-
Glucose	-	-	-	-	-	-	-
Hemoglobin	-	-	-	-	-	-	-
Isoproterenol	-	-	-	-	-	-	-
Lidocaine	-	-	-	-	-	-	-
Methylphenidate	-	-	-	-	-	-	-
N-Methyl-Ephedrine	-	-	-	-	-	-	-
(+)-Naproxen	-	-	-	-	-	-	-
Oxalic acid	-	-	-	-	-	-	-
Penicillin-G	-	-	-	-	-	-	-
Pheniramine	-	-	-	-	-	-	-
Phenothiazine	-	-	-	-	-	-	-
L-Phenylephrine	-	-	-	-	-	-	-
ß-phenylethylamine	-	-	-	-	-	-	-
Procaine	-	-	-	-	-	-	-
Quinidine	-	-	-	-	-	-	-
Ranitidine	-	-	-	-	-	-	-
Sodium Chloride	-	-	-	-	-	-	-

Sulindac	-	-	-	-	-	-	-
Thioridazine	-	-	-	-	-	-	-
Trifluoperazine	-	-	-	-	-	-	-
Tyramine	-	-	-	-	-	-	-
Vitamin C	-	-	-	-	-	-	-

The compounds were dissolved in 150% cutoff samples to the concentration of 100 ug/ml to evaluate any negative interference effects. An unaltered sample was used as a control. Results are listed below

Compound	**THC**	**COC**	**OPI**	**PPX**	**OXY**	**BAR**	**BZO**
Control	+	+	+	+	+	+	+
Acetaminophen	+	+	+	+	+	+	+
Acetone	+	+	+	+	+	+	+
Albumin	+	+	+	+	+	+	+
Ampicillin	+	+	+	+	+	+	+
Amitriptyline	+	+	+	+	+	+	+
Aspartame	+	+	+	+	+	+	+
Aspirin	+	+	+	+	+	+	+
Atropine	+	+	+	+	+	+	+
Benzocaine	+	+	+	+	+	+	+
Bilirubin	+	+	+	+	+	+	+
Caffeine	+	+	+	+	+	+	+
Chloroquine	+	+	+	+	+	+	+
Chlorpheniramine	+	+	+	+	+	+	+
Creatine	+	+	+	+	+	+	+
Dexbrompheniramine	+	+	+	+	+	+	+
Dextromethorphan	+	+	+	+	+	+	+
4+Dimethylamino antipyrine	+	+	+	+	+	+	+
Dopamine	+	+	+	+	+	+	+
(+/+)+Ephedrine	+	+	+	+	+	+	+
Erythromycin	+	+	+	+	+	+	+
Ethanol	+	+	+	+	+	+	+
Furosemide	+	+	+	+	+	+	+
Guaiacol Glyceryl Ether	+	+	+	+	+	+	+
Glucose	+	+	+	+	+	+	+
Hemoglobin	+	+	+	+	+	+	+
Isoproterenol	+	+	+	+	+	+	+
Lidocaine	+	+	+	+	+	+	+
Methylphenidate	+	+	+	+	+	+	+
N+Methyl+Ephedrine	+	+	+	+	+	+	+
(+)+Naproxen	+	+	+	+	+	+	+
Oxalic acid	+	+	+	+	+	+	+
Penicillin+G	+	+	+	+	+	+	+
Pheniramine	+	+	+	+	+	+	+
Phenothiazine	+	+	+	+	+	+	+
L+Phenylephrine	+	+	+	+	+	+	+
ß+phenylethylamine	+	+	+	+	+	+	+

Procaine	+	+	+	+	+	+	+
Quinidine	+	+	+	+	+	+	+
Ranitidine	+	+	+	+	+	+	+
Sodium Chloride	+	+	+	+	+	+	+
Sulindac	+	+	+	+	+	+	+
Thioridazine	+	+	+	+	+	+	+
Trifluoperazine	+	+	+	+	+	+	+
Tyramine	+	+	+	+	+	+	+
Vitamin C	+	+	+	+	+	+	+

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

To test for potential positive/and or negative interference from endogenous conditions the following studies were performed:

To evaluate any possible positive interference of pH, acid or base was added to 50% cutoff samples to obtain samples with pH values from 3 to 9. An unaltered sample was used as a control. Results were as follows.

pH	**THC**	**COC**	**OPI**	**PPX**	**OXY**	**BAR**	**BZO**
7 (Control)	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-
4.5	-	-	-	-	-	-	-
5.5	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-

To evaluate any possible negative interference of pH, acid or base was added to 150% cutoff samples to obtain samples with pH values from 3 to 9. An unaltered sample was used as a control. Results were as follows.

pH	**THC**	**COC**	**OPI**	**PPX**	**OXY**	**BAR**	**BZO**
7 (Control)	+	+	+	+	+	+	+
3	-	-	-	-	-	-	-
4.5	+	+	+	+	+	+	+
5.5	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+

To evaluate any possible positive interference of specific gravity, distilled water or sodium chloride was added to 50% cutoff sample to obtain samples with specific gravity values from 1.002 to 1.03. An unaltered sample was used as a control. Results were as follows.

Specific gravity	THC	COC	OPI	PPX	OXY	BAR	BZO
1.01 (Control)	-	-	-	-	-	-	-
1.002	-	-	-	-	-	-	-
1.02	-	-	-	-	-	-	-
1.03	-	-	-	-	-	-	-

To evaluate any possible negative interference of specific gravity, distilled water or sodium chloride was added to 150% cutoff sample to obtain samples with specific gravity values from 1.002 to 1.03. An unaltered sample was used as a control. Results were as follows.

Specific gravity	THC	COC	OPI	PPX	OXY	BAR	BZO
1.01 (Control)	+	+	+	+	+	+	+
1.002	+	+	+	+	+	+	+
1.02	+	+	+	+	+	+	+
1.03	+	+	+	+	+	+	+

The sponsor did not evaluate the effects of albumin on the assay.

f. Assay cut-off:

The identified cutoff concentration of the assays for THC and cocaine metabolite are recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA). The cutoff chosen for the opiates assay is different than that recommended by SAMHSA. No recommendations have been made by SAMHSA for propoxyphene, oxycodone, barbiturates, or benzodiazepines.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision and sensitivity sections, above.

2. Comparison studies:
    a. *Method comparison with predicate device:*

Forty presumed negative samples were collected from volunteer donors at the sponsor's facility and tested for all seven analytes by the candidate device and the predicate devices. All forty samples were negative for all analytes using the candidate device and the predicate devices. In a separate study, seven drug groups were evaluated by the candidate device, GC/MS and the predicate devices. The groups consisted of the following:

THC group:	95 samples (21 neg, 74 pos)
COC group:	86 samples (22 neg, 64 pos)
OPIA group:	101 samples (31 neg, 70 pos)
PPX group:	115 samples (31 neg, 84 pos)
OXY group:	74 samples (21 neg, 53 pos)
BAR group:	83 samples (21 neg, 62 pos)
BZO group:	79 samples (37 neg, 42 pos)

Sample description: Unaltered clinical urine samples were evaluated. An additional 267 diluted samples were also included in the study. The samples were prepared by diluting clinical samples with high drug concentrations with drug-free urine. This was done in order to obtain samples near the cutoff concentration of the assay, because the sponsor was not able to obtain unaltered samples near the cutoff.

Samples previously analyzed by GC-MS were selected to be analyzed by the candidate device and the predicate. Results were grouped according to GC-MS concentration. NOTE: the sponsor states that samples were run in duplicate on the candidate device. If there was a discrepancy between the two results the sample was run a third time in order to obtain the final result. The number of times where a third result was required is as follows:

THC group: 1/95 samples with GC-MS concentration of 54 ng/mL

COC group: 2/86 samples with GC-MS concentrations of 305 and 313 ng/mL

OPIA group: none

PPX group: 1/115 samples with GC-MS concentration of 284 ng/mL

OXY group: none

BAR group: none

BZO group: none

In three of the four cases where a third replicate was run, the final result reported was in agreement with the GC-MS concentration.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. More than 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration for all analytes.

The study was performed at the manufacturer's facility by one member of the manufacturer's staff.

Candidate Device Results vs. Predicate Device Results - THC

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	71	0
Negative by Candidate Device	1	63

% Agreement among positives is 100%
% Agreement among negatives is 98%

Candidate Device Results vs. stratified GC/MS Values - THC

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	8	63
Negative	12	9	2	0

GC/MS values used to categorize samples in this table are based on the concentration of THC found in the sample.

% Agreement among positives is 97%
% Agreement among negatives is 95%
NOTE: one sample was run in triplicate to obtain a final result

Candidate Device Results vs. Predicate Device Results - COC

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	64	1
Negative by Candidate Device	0	61

% Agreement among positives is 98%
% Agreement among negatives is 100%

Candidate Device Results vs. stratified GC/MS Values - COC

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	8	54
Negative	11	9	1	0

GC/MS values used to categorize samples in this table are based on the concentration of BE found in the sample.

% Agreement among positives is 98%
% Agreement among negatives is 91%
NOTE: two samples were run in triplicate to obtain a final result

Candidate Device Results vs. Predicate Device Results - OP

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	69	1
Negative by Candidate Device	1	70

% Agreement among positives is 99%
% Agreement among negatives is 99%

Candidate Device Results vs. stratified GC/MS Values - OP

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	9	59
Negative	15	14	2	0

GC/MS values used to categorize samples in this table are determined by adding together codeine and morphine values.

% Agreement among positives is 97%
% Agreement among negatives is 94%

Candidate Device Results vs. Predicate Device Results - PPX

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	81	2
Negative by Candidate Device	4	68

% Agreement among positives is 98%
% Agreement among negatives is 94%

Candidate Device Results vs. stratified GC/MS Values - PPX

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	7	74
Negative	20	9	3	0

GC/MS values used to categorize samples in this table are based on the concentration of propoxyphene found in the sample.

% Agreement among positives is 96%
% Agreement among negatives is 94%
NOTE: one sample was run in triplicate to obtain a final result

Candidate Device Results vs. Predicate Device Results - OXY

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	52	1
Negative by Candidate Device	2	59

% Agreement among positives is 98%
% Agreement among negatives is 97%

Candidate Device Results vs. stratified GC/MS Values - OXY

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	8	43
Negative	11	8	2	0

GC/MS values used to categorize samples in this table are based on the concentration of oxycodone found in the sample.

% Agreement among positives is 96%
% Agreement among negatives is 90%

Candidate Device Results vs. Predicate Device Results - BAR

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	62	1
Negative by Candidate Device	1	59

% Agreement among positives is 98%
% Agreement among negatives is 98%

Candidate Device Results vs. stratified GC/MS Values - BAR

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	10	51
Negative	10	9	1	0

GC/MS values used to categorize samples in this table are based on the concentration of butabarbital found in the sample.

% Agreement among positives is 98%
% Agreement among negatives is 90%

Candidate Device Results vs. Predicate Device Results - BZO

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	44	0
Negative by Candidate Device	0	75

% Agreement among positives is 100%
% Agreement among negatives is 100%

Candidate Device Results vs. stratified GC/MS Values - BZO

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	9	32
Negative	25	9	1	0

GC/MS values used to categorize samples in this table are based on the concentration of oxazepam found in the sample.

% Agreement among positives is 98%
% Agreement among negatives is 92%

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   Not applicable.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.